

Def & ref



Los Altos Hills, CA 94024
March 8, 2010

Office of Petitions
Mail Stop Petition
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Subject: Petition to Withdraw Holding of Abandonment, Application No. 10/826,232

I request withdrawal of the holding of abandonment for patent application number 10/826,232.

I received a Notice of Abandonment on 03/04/10. However, the application never should have gone abandoned. All required documents (a copy of each document is appended herewith) were submitted within the specified timeframe on 11/23/09:

- RCE Transmittal Letter
- Petition for Extension of Time (1 month)
- Certificate of Mailing
- Amendment
- Check in the amount of \$470
- Receipt-acknowledgement postcard

The patent application number was entered incorrectly by me as 10/826,233 on one of the submitted documents, the RCE Transmittal Letter. All other submitted documents carried the correct application number, and all documents carried the correct inventor name. Finally, the Amendment listed the Confirmation Number as 9638, the same as the parent application. However, my call today to the Petition Helpdesk confirmed that a USPTO clerical error resulted in all of the documents that I submitted on 11/23/09 incorrectly being appended to application 10/826,233. Furthermore, I learned that application 10/826,233 already had been assigned a Serial Number at the time of my submittal on 11/23/09, which should have prevented the processing of an RCE application and fee.

I can be reached at the address above, by telephone at (650) 949-2219, or by email at carol.tosaya@gmail.com.

Respectfully,

Carol A. Tosaya

Carol A. Tosaya
Inventor, application number 10/826,232



11-24-09

1 Filed

RCE

PTO/SB/30 (07-09)

Approved for use through 07/31/2012. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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Request for Continued Examination (RCE) Transmittal

Address to:
Mail Stop RCE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Application Number	10/826,237 <u>2</u>
Filing Date	April 16, 2004
First Named Inventor	Carol A. Tosaya
Art Unit	3767
Examiner Name	Maria E. Doukas
Attorney Docket Number	D-03020A

This is a Request for Continued Examination (RCE) under 37 CFR 1.114 of the above-identified application. Request for Continued Examination (RCE) practice under 37 CFR 1.114 does not apply to any utility or plant application filed prior to June 8, 1995, or to any design application. See Instruction Sheet for RCEs (not to be submitted to the USPTO) on page 2.

1. **Submission required under 37 CFR 1.114** Note: If the RCE is proper, any previously filed unentered amendments and amendments enclosed with the RCE will be entered in the order in which they were filed unless applicant instructs otherwise. If applicant does not wish to have any previously filed unentered amendment(s) entered, applicant must request non-entry of such amendment(s).

a. ☐ Previously submitted. If a final Office action is outstanding, any amendments filed after the final Office action may be considered as a submission even if this box is not checked.

i. ☐ Consider the arguments in the Appeal Brief or Reply Brief previously filed on _____

ii. ☐ Other _____

b. ☒ Enclosed

i. ☒ Amendment/Reply

ii. ☐ Affidavit(s)/ Declaration(s)

iii. ☐ Information Disclosure Statement (IDS)

iv. ☒ Other Petition for Extension of Time (1 mo.)

2. **Miscellaneous**

☐ Suspension of action on the above-identified application is requested under 37 CFR 1.103(c) for a period of _____ months. (Period of suspension shall not exceed 3 months; Fee under 37 CFR 1.17(i) required)

☐ Other _____

3. **Fees** The RCE fee under 37 CFR 1.17(e) is required by 37 CFR 1.114 when the RCE is filed. The Director is hereby authorized to charge the following fees, any underpayment of fees, or credit any overpayments, to

a. ☐ Deposit Account No. _____

i. ☒ RCE fee required under 37 CFR 1.17(e) \$405.00

ii. ☒ Extension of time fee (37 CFR 1.136 and 1.17) \$65.00

iii. ☐ Other _____

b. ☒ Check in the amount of \$ 470.00 enclosed

c. ☐ Payment by credit card (Form PTO-2038 enclosed)

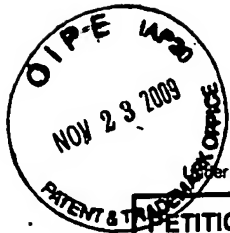
WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED			
Signature	<u>Carol A. Tosaya</u>	Date	11/23/2009
Name (Print/Type)	Carol A. Tosaya	Registration No.	pro se

CERTIFICATE OF MAILING OR TRANSMISSION			
I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop RCE, Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450 or facsimile transmitted to the U.S. Patent and Trademark Office on the date shown below.			
Signature	<u>Carol A. Tosaya</u>	Date	11/23/2009
Name (Print/Type)	Carol A. Tosaya	Date	11/23/2009

This collection of information is required by 37 CFR 1.114. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.



Under the paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(a) FY 2009 <i>(Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).)</i>		Docket Number (Optional) D-03020A	
Application Number 10/826,232 ✓		Filed April 16, 2004	
For Non-Contact Damage-Free Ultrasonic Cleaning of Implanted or Natural Structures Having Moving Parts			
Art Unit 3787		Examiner Maria E. Doukas	
This is a request under the provisions of 37 CFR 1.136(a) to extend the period for filing a reply in the above identified application. The requested extension and fee are as follows (check time period desired and enter the appropriate fee below):			
	<u>Fee</u>	<u>Small Entity Fee</u>	
<input checked="" type="checkbox"/> One month (37 CFR 1.17(a)(1))	\$130	\$65	\$ 65.00
<input type="checkbox"/> Two months (37 CFR 1.17(a)(2))	\$490	\$245	\$ _____
<input type="checkbox"/> Three months (37 CFR 1.17(a)(3))	\$1110	\$555	\$ _____
<input type="checkbox"/> Four months (37 CFR 1.17(a)(4))	\$1730	\$865	\$ _____
<input type="checkbox"/> Five months (37 CFR 1.17(a)(5))	\$2350	\$1175	\$ _____
<input checked="" type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27.			
<input checked="" type="checkbox"/> A check in the amount of the fee is enclosed.		11/25/2009 CCHAUI	00000015 10826233
<input type="checkbox"/> Payment by credit card. Form PTO-2038 is attached.		02 FC:2251	65.00 0P
<input type="checkbox"/> The Director has already been authorized to charge fees in this application to a Deposit Account.			
<input type="checkbox"/> The Director is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account Number _____.			
WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.			
I am the <input checked="" type="checkbox"/> applicant/inventor.			
<input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed (Form PTO/SB/96).			
<input type="checkbox"/> attorney or agent of record. Registration Number _____			
<input type="checkbox"/> attorney or agent under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____			
<u>Carol A. Tosaya</u>		11/23/2009	
Signature		Date	
Carol A. Tosaya		(650) 949-2219	
Typed or printed name		Telephone Number	

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below.

☒ Total of 2 forms are submitted.

This collection of information is required by 37 CFR 1.136(a). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 6 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

AMENDMENTS TO THE CLAIMS

The following is a listing of claims presently in the application, wherein Claims 1-88 are canceled and are replaced with substantially reduced new Claims 89-102:

Claims 1-88 (canceled)

89. (New) Invasive or minimally invasive apparatus for removal, breakdown or erosion of undesirable deposits present on, at or in actuating bodily implants or actuating bodily-members or organs of a patient comprising:

at least one distal acoustic emitter capable of directing acoustic energy toward a target bearing said deposits for the purpose of removing at least some of said deposit and recovering a desired degree of actuation;

an exciter to power and control the emitters acoustic operation;

the emitter situated inside of or behind a deformable or soft standoff, the standoff at least one of (i) preventing or inhibiting direct emitter-target contact, (ii) allowing for gentle stoppage or suppression of the targets actuation for deposit removal, and (iii) allowing for passage of the emitter into or through the actuator without damaging the actuator;

a proximally grippable scope, catheter, handle, guidewire, sheath or a gripping robot distally supporting the emitter and allowing a practitioner to control acoustic coupling of and use of the emitter on the target;

wherein by actuating is specifically meant that the implant or body member being treated for deposit has (a) adjacent, joined or mating portions which normally at least one of swing, hinge, pivot, distend, or flex relative to each other at least once or (b) mating parts which are plugged, connected, threaded or passed in-to or through each other at least once; and

said deposit either currently negatively impacts normal actuation or threatens to worsen such that it eventually degrades actuation, thereby negatively impacting the patient.

90. (New) The apparatus of claim 89 wherein said actuation comprises any one or more of:

desirable swinging, pivoting, hinging or occluding;
desirable plugging, unplugging, threading or connecting; or
desirable flexing or distending.

91. (New) The apparatus of Claim 89 wherein the implant or member is a cardiac, arterial or lymphatic valve of any natural, prosthetic or implanted type or is an implanted connector of any type.

92. (New) The apparatus of Claim 89 wherein a drug or chemical agent is employed at any time to aid in the acoustic removal of the deposit material in any manner.

93. (New) The apparatus of Claim 89 wherein the acoustic power employed is sufficient to cause at least one of blood streaming, blood or deposit cavitation, deposit erosion or deposit-heating useful in said removal.

94. (New) The apparatus of Claim 89 wherein acoustic power is being delivered continuously or in a pulsed manner, either gated or not gated to the heartbeat.

95. (New) The apparatus of Claim 89 wherein either or both of imaging guidance or acoustic signatures are employed to any of plan, assess, guide, gate or monitor a removal task.

96. (New) The apparatus of Claim 95 where said imaging or acoustic signatures specifically monitor an aspect of actuation state or performance.

97. (New) The apparatus of Claim 95 wherein the specific location of preexisting deposits on or at an actuator is known via said imaging or signature and targeted meaning the fouled portion of the actuator is specifically preferentially targeted.

98. (New) The apparatus of Claim 95 wherein the imaging or signature acquisition means is integrated with or proximal to the emitter.

99. (New) The apparatus of Claim 89 wherein any one of the following is employed:

- a cavitation enhancing agent, including microbubbles;
- a physical trap or drain to safely catch or route deposit debris after removal.

100. (New) The apparatus of Claim 89 wherein a deposit includes one or more of:

- pannus, bacteria, endocarditis related growths, calcium containing deposits, fat containing deposits, fungus, plaque, fibrous containing deposits, thrombus, clot related materials, any flow-restricting deposits or biofilms.

101. (New) The apparatus of Claim 89 wherein the actuation occurs between one or more of:

- two or more portions of one or more natural body parts;
- two or more portions of one or more implants regardless of whether the implant(s) is constituted of tissue or engineering materials; or
- a natural body part and an implant part.

102. (New) The apparatus of Claim 89 wherein the standoff comprises a saline filled balloon.

REMARKS

Claims 89-102 are in the application. Claims 1-88 have been canceled. Support for the new claims is found throughout the specification, including the claims as originally filed.

The inventors teach degradation and potential loss of the desirable actuation ability of natural and implanted bodily members being harmful to patients. Specific taught examples of susceptible actuators include swinging, hinging, pivoting and occluding members (e.g., natural and artificial valves) as well as plugging, unplugging, connecting, distending and flexing members (such as plugging electrical connectors or flexing (to occlude) valve leaflets). Also, implanted members which desirably pass-through or pass-into other members or are threaded into other implanted members are specifically taught. In all of these examples, the loss of or degradation of desirable actuation directly contributes to a health hazard such as for a valve no longer functioning or an implanted connector which cannot be engaged or disengaged. It should also be clearly apparent from new Claim 1 that fouled or foulable stents or locally occluded lumens do not involve fouled or foulable actuators and that our claimed invention always includes a damage-reducing standoff which can be directly presented to or even passed-through the cleanable actuating target.

Specific citations from teaching supporting the above and the new claims herein:

"Actuation, actuating": page 3, lines 23, 25; page 4, lines 17, 24, 29, 34; page 5, lines 1, 2, 4, 5, 10, 11, 12, 28; page 6, line 6; page 7, lines 18, 19, 31; page 8, line 8;

"Swing, swinging": page 4, line 3; page 11, lines 7, 11, 12;

"Occlude, occluding": page 2, lines 2, 4-5; page 4, line 3; page 9, line 24; page 11, lines 7, 31, 32; page 12, lines 1, 5, 7, 23, 24; page 15, line 32; page 19, lines 17, 20;

"Hinged or hinging": page 11, line 12; page 12, lines 17, 27; page 19, lines 18;

"Plugging, unplugging" (as for mating members): page 5, line 10;

"Flexing, flexural or distending/distention": page 12, line 27; page 24, line 1; page 5, lines 14, 28; page 7, lines 17, 32; page 8, line 8;

"Passing through/into, passage-of through/into or threading": page 12, line 26, page 12, line 27;

"pivot or pivoting": page 2, line 1; page 11, line 12; page 12, lines 17, 27.

In the Office Action dated July 24, 2009, Claims 1-11, 13, 18-23, 26-27, 31-35, 37-41, 45, 48-50, 53, 57-64, 73, 74, and 76-84 were finally rejected under 35 USC 102(b) as being anticipated by Olsson (U.S. Patent 5,713,831), while Claims 28, 29, 47, 65-69, 71, 72, and 75 were finally rejected under 35 USC 103(a) as being unpatentable over Olsson.

General Comments Regarding the Office Action and Cited Art Cited

(a) We previously claimed in our Claim 1 deposit removal from moving parts. We now understand that wording was too broad and what we mean to focus on and did indeed specifically teach repeatedly is actuating parts, per new Claim 89, wherein by actuating is specifically meant that the implant or body member has (a) adjacent, joined or mating portions which normally at least one of swing, hinge, pivot, distend, or flex relative to each other at least once or (b) mating parts which are plugged, connected, threaded or passed into or through each other. Thus, for example, Olsson's teachings (as well as others) involve clearing static thrombi in plugged lumens and do not involve a compromised desirable actuator. Nor does any cited art involve cleaning of stents, as the stent is not an actuator as-placed.

Thus, for a thrombus, such as Olsson's, the motion (moving) of the overall heart is irrelevant as he does not discuss any actuating part needing cleaning. What clearly does fit our definition of actuating, for example, are valves with mating moving parts whose parts can seize or gum-up if they have debris on or in them. It does not matter whether the valve is a heart valve (wherein the heart itself also moves with the whole valve) or the valve is a leg valve (wherein the valve as a whole does not move with respect to the leg). In both cases, a locally actuating valve component is prevented from failing.

(b) Further beyond item (a) above, we include in our new Claim 89 our stand-off, which allows one or more of damage-free treatment of the valve from a stand-off distance (or even from within), allows passage through the valve of the emitter without valve damage, and allows gentle but forced temporary stoppage of the

valve's actuation. This is a fundamental construction limitation. Note that the standoff is combined with the cleaning of a fragile actuator which would otherwise potentially be damaged by the cleaning attempt. In the case of a saline filled balloon standoff, its size is limited only by where it must pass uninflated (delivery through lumens) and inflated (standing off from, stopping-of or passing-through an actuator), so it will be utilized in a range of sizes. There is substantial art on similar balloons used for unrelated purposes such as forceful expansion of lumens and physical displacement of blood for visualization purposes.

(c) As further limitations in our new reduced Claims 89-102, please note the following:

Claim 91, wherein the actuator is a valve or connector of some type

Claim 93, wherein the acoustic power is high enough to cause streaming or cavitation (Olsson, for example, is explicitly way below this power level);

Claim 95, wherein acoustic imaging and/or acoustic signatures are employed to monitor or control the use of the apparatus;

Claim 96, wherein actuation itself or a state thereof is specifically monitored;

Claim 97, wherein deposits within an actuator portion are specifically targeted (as opposed to a shotgun wide-area treatment of Olsson); and

Claim 99, wherein the debris is routed away safely in a controlled manner and/or eroded using the help of microbubbles.

(d) Our new Claim 89 is for invasive/minimally invasive devices only involving the need for a catheter or scope, for example, and requiring our inventive standoff. Note that a noninvasive device would not require a standoff or a scope/catheter and would be much larger (Olsson external device)

So, our revised and reduced claims would also cover medical device implants such as a previously implanted electrical connector which needs to be cleaned and then disengaged upon a later surgery, for example. In that case, the mating connector parts are the actuating parts (relative to each other) and the connector is desirably normally connectable/disconnectable (actuatable) if not fouled.

Note again that any art involving cleaning fouled stents, for example, is not relevant because there are no desirably actuating parts in a placed stent. Any art involving cleaning lumens (such as plaques therefrom) is not relevant either, because there is not any desirable actuation being interfered with per our definition.

The application is considered to be in condition for allowance. The Examiner is respectfully requested to take such action. If the Examiner has any questions, she is invited to contact the undersigned at the below-listed telephone number.

Respectfully submitted,

Carol Tosaya

November 23, 2009

Carol A. Tosaya, pro se

24871 Olive Tree Lane
Los Altos Hills, CA 94024

Telephone: (650) 949-2219



PATENT

D-03020A

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Confirmation No.: 9638

Carol A. Tosaya et al

Serial No.: 10/826,232

Group Art Unit: 3767

Filed: April 16, 2004

Examiner: M. E. Doukas

For: Non-Contact Damage-Free Ultrasonic Cleaning of
Implanted or Natural Structures Having Moving
Parts and Located in a Living Body

Mail Stop RCE

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

AMENDMENT TO ACCOMPANY RCE

Sir:

This Amendment is in response to the Office Action dated July 24, 2009, finally rejecting Claims 1-11, 13, 18-23, 26-29, 31-41, 45, 47-50, 53, 57-69, and 71-84, and accompanies a Request for Continued Examination. A Petition for Extension of Time (one month) accompanies this Amendment.



Dear Madam/Sir: Express Mail Label: EH 814283357

Please acknowledge receipt of the following
document(s) re U.S. Patent Application
Docket No. D-03020A ; Auy: David W. Collins
Serial No. 10/826230Z Filed: 4/16/2004
Inventor(s): Tosaya et al

Title: Non-Contact Damage-Free Ultrasonic
Cleaning of Implanted or Natural
Structures Having Moving Parts and
Located in a Living Body



Documents(s): ☒ RCE Transmittal Letter
☒ Petition for Extension of Time (1 month)
☒ Certificate of Mailing
☒ Amendment
☒ Check in the amount of \$470.00
☒ One receipt postcard

Date of Mailing: 11/23/2009